The Swedish Patent Offic
PCT International Application

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CLAIMS

1. Process for the continuous purification and concentration of leukocytes from blood, characterized in that said process comprises the following steps:

(a) separating plasma from the blood by filtration in order to achieve a filtered buffy coat fraction;

(b) adding an aqueous solution, which is hypotonic in relation to plasma, to the buffy coat fraction from step (a), in order to achieve lysation of erythrocytes contained in the buffy coat fraction;

(c) mixing the buffy coat fraction and the aqueous hypotonic solution from step (b) in a mixing device;

(d) leading the mixture from step (c) through a retention vessel;

(e) leading the mixture from step (d) through a centrifuge in order to separate the leukocytes ;

(f) collecting the separated leukocytes from step (e).

2. Process according to claim 1, characterized in that a buffy coat fraction, obtained from blood, is used instead of blood in step (a) and plasma is removed from this buffy coat fraction by filtration.

3. Process according to claim 1 ~~or 2~~, characterized in that in step (b) the aqueous hypotonic solution is ammonium chloride.

4. Process according to Claim 1 ~~any of the claims 1 - 3~~, characterized in that the filtration is performed by leading the blood through a membrane filter with a pore size in the interval of 0.1 - 1.0 µm.

5. Process according to claim 4, characterized in that the filtration is performed by leading the blood through a membrane filter with a pore size in the interval of 0.4 - 0.6 µm.

6. Process according to Claim 1 ~~any of the claims 1 - 5~~, characterized in that the retention vessel is designed in a way resulting in a retention time for the mixture in step (d) of about 0.5 - 10 minutes.

AMENDED SHEET

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7. Process according to ~~any of the claims 1 - 6,~~ characterized in that the leukocytes collected in step (f) are subjected to a second lysis step.

8. Process according to claim 1 ~~any of the claims 1 - 7,~~ characterized in that the leukocytes collected in step (f) are incubated in a bioreactor for interferon production.

9. Process according to claim 1 ~~or 2,~~ characterized in that the plasma separated in step (a) is recovered.

10. Process according to claim 1 ~~any of the claims 1 - 7,~~ characterized in that the process is automatically operated and adapted for clean in place (CIP) cleaning and ~~(SIP) sanitation in place~~.

11. Process according to claim 1 ~~any of the preceding claims,~~ characterized in that the blood is human blood.

12. Apparatus for continuous purification and concentration of leukocytes, from blood, characterized in that said apparatus includes the following means:

(i) a membrane filter means for separating plasma from the blood by filtration in order to achieve a filtered buffy coat fraction;

(ii) a static mixer means connected to said membrane filter means and receiving said buffy coat fraction for mixing the buffy coat fraction and an aqueous hypotonic solution in order to achieve lysation of erythrocytes contained in the buffy coat fraction of the mixture;

(iii) a retention vessel means, connected to said static mixer means for receiving the mixture therefrom and designed in a way for the mixture to become homogeneous;

(iv) a centrifuge means connected to said retention vessel means and arranged to separate the leukocytes from the mixture from the retention vessel.

13. Apparatus according to claim 12, characterized in that, a buffy coat fraction, obtained from blood, is used in stead of blood and plasma is removed from this buffy coat fraction by filtration.

14. Apparatus according to claim 12, characterized in that the aqueous hypotonic solution is ammonium chloride.

15. Apparatus according to claim 12, characterized in that the membrane filter means is a filter with a pore size in the interval of 0.1 - 1.0 µm.

16. Apparatus according to claim 14, characterized in that the membrane filter means is a filter with a pore size in the interval of 0.4 - 0.6 µm.

17. Apparatus according to claim 12, characterized in that the retention vessel means is designed in a way resulting in a retention time for the mixture in the retention vessel of about 0.5 - 10 minutes.

18. Apparatus according to claim 12, characterized in that the centrifuge is adapted to continuous or semi-continuous separation of the leukocytes.

19. Apparatus according to claim 12, characterized in that said apparatus is equipped for cleaning and sanitation, which cleaning and sanitation does not require the dismantling of the equipment, so called clean in place (CIP) and sanitation in place (SIP).

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